NANOBIOBITIX RECEIVES THE 2019 PRIX GALIEN AWARD FOR FIRST-IN-CLASS HENSIFY®

- HENSIFY® is a first-in-class “radioenhancer” that consists of hafnium oxide nanoparticles which increases the tumor-killing effect of radiation therapy without increasing damage to health cells
- HENSIFY® is the first product of its kind to receive European market approval (CE Marking)
- The product is in development globally across 15 clinical trials, with the Company’s primary focus centering on global registration for the treatment of Head and Neck cancers

“We are thrilled to receive the 2019 Prix Galien for HENSIFY®. It is both humbling and rewarding to know that the efforts of our team and our partners, over more than 15 years, have been recognized in this way. At Nanobiotix, we remain committed to changing the face of cancer therapy through disruptive innovation, all with the goal of significantly improving outcomes for patients around the world.” – Laurent Levy, CEO of Nanobiotix

Paris, France ; Cambridge, Massachusetts (USA) : December 16, 2019 - NANOBIOBITIX (Euronext: NANO - ISIN: FR0011341205 – the “Company”), a clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, today announced receipt of the French 2019 Prix Galien Award for Most Innovative MedTech. The Company’s lead product, HENSIFY® (NBTXR3) brand name for the treatment of locally advanced Soft Tissue Sarcoma (STS), was recognized after receiving European market approval (CE marking, DM class III, on April 2, 2019) earlier this year. The Prix Galien Award recognizes outstanding biomedical and medical technology product achievements that improve the human condition.

HENSIFY® is a first-in-class “radioenhancer” consisting of an aqueous suspension of crystalline hafnium oxide nanoparticles. The product is administered only once, directly into the tumor, before a patient’s first radiotherapy session. After intratumoral injection, the nanoparticles penetrate the tumor cells and, when activated by ionizing radiation, deliver a larger energy deposit within the tumor where the nanoparticles are present, thereby increasing the tumor-killing effect of treatment without increasing damage to surrounding healthy tissues. HENSIFY® has a universal, physical mode of action and is inert within the human body outside of the presence of ionizing radiation.

The product is approved in Europe for the treatment of Soft Tissue Sarcoma (STS). Positive results from the Company’s phase III STS study were featured the August 2019 edition of The Lancet Oncology.

Moving forward, the Company is engaged in global clinical development of the product across fifteen (15) clinical trials in STS and other indications with a primary focus on global registration for the treatment of Head and Neck cancers. These trials include the expansion phase of a European phase I evaluating the safety and feasibility of NBTXR3 activated by radiation therapy (Study NBTXR3-102); an immuno-oncology (I/O) basket trial (Study NBTXR3-1100) which evaluates NBTXR3 in combination with anti-PD-1 in the United States (US); phase I trials evaluating NBTXR3 activated by radiation therapy for the treatment of liver and prostate cancer; a partnership with PharmaEngine in Asia evaluating NBTXR3 in combination with cisplatin; and a clinical collaboration with The University of Texas MD Anderson Cancer Center (MD Anderson) including nine (9) trials across several indications.

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About the PRIX GALIEN
Created in France in 1970, the Prix Galien is the most prestigious award in the field of pharmaceutical research and innovation. Referred to as the “Nobel Prize of pharmaceutical research, it recognizes the efforts and achievements of pharmaceutical research and development.
About NBTXR3
NBTXR3 is a first-in-class product designed to destroy tumors through physical cell death when activated by radiotherapy. NBTXR3 has a high degree of biocompatibility, requires one single administration before the first radiotherapy treatment session, and has the ability to fit into current worldwide standards of radiation care. The physical mode of action of NBTXR3 makes it applicable across solid tumors such as lung, prostate, liver, glioblastoma, and breast cancers.

NBTXR3 is actively being evaluated in head and neck cancer with locally advanced squamous cell carcinoma of the oral cavity or oropharynx in elderly and frail patients unable to receive chemotherapy or cetuximab with limited therapeutic options. Promising results have been observed in the phase I/II trial regarding local control. In the United States, the company has started the regulatory process in regard to the clinical authorization to the phase II/III in locally advanced head and neck cancers.

Nanobiotix is also running an Immuno-Oncology development program. The Company received approval FDA to launch a clinical trial of NBTXR3 activated by radiotherapy in combination with anti-PD-1 antibodies in locoregional recurrent (LRR) or recurrent and metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) and lung or liver metastasis (mets) with HNSCC not amenable to re-irradiation or non-small cell lung cancer (NSCLC) as the primary tumor.

The other ongoing NBTXR3 trials are treating patients with liver cancers (hepatocellular carcinoma and liver metastasis), locally advanced or unresectable rectal cancer in combination with chemotherapy, head and neck cancer in combination with concurrent chemotherapy, and prostate adenocarcinoma. Furthermore, the company has a large-scale, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center (9 new phase I/II clinical trials in the United States) to evaluate NBTXR3 across head and neck, pancreatic, thoracic, lung, gastrointestinal and genitourinary cancers.

About NANOBIOBITX: www.nanobiotix.com
Incorporated in 2003, Nanobiotix is a leading, clinical-stage nanomedicine company pioneering new approaches to significantly change patient outcomes by bringing nanophysics to the heart of the cell.

The Nanobiotix philosophy is rooted in designing pioneering, physical-based approaches to bring highly effective and generalized solutions to address unmet medical needs and challenges.

Nanobiotix’s first-in-class, proprietary lead technology, NBTXR3, aims to expand radiotherapy benefits for millions of cancer patients. Nanobiotix’s Immuno-Oncology program has the potential to bring a new dimension to cancer immunotherapies.


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This press release contains certain forward-looking statements concerning Nanobiotix and its business, including its prospects and product candidate development. Such forward-looking statements are based on assumptions that Nanobiotix considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the reference document of Nanobiotix registered with the French Financial Markets Authority (Autorité des Marchés Financiers) under number R.19-018 on April 30, 2019 (a copy of which is available on www.nanobiotix.com) and to the development of economic conditions, financial markets and the markets in which Nanobiotix operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Nanobiotix or not currently considered material by Nanobiotix. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Nanobiotix to be materially different from such forward-looking statements.